510(k) Summary

RJL Systems, Inc.
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AUG - 2 2007

1) Identification of the Device:
Proprietary – Trade Name: BC body composition software
Common Name: Body Composition Analyzer
Classification Number: 21 CFR 870.2770
Classification Name: Impedance Plethysmograph
Product Code: MNW

2) Equivalent Legally Marketed Devices:
RJL Systems; BIA-103 (K862383)
Impedimed; DF50 (K050395)
BodyStat; QuadScan 4000 (K002835)

3) Indications for use
BC is a software accessory for RJL Systems Quantum-II, Quantum-X, Quantum Desktop, and Quantum-III. It requires a separate personal computer running the Windows Operating System. To automatically retrieve data from the Quantum Desktop and Quantum-III analyzers, the computer must have an available serial port.

Indications:
Calculation and Historical Tracking of:

- Actual Impedance
- Actual Phase Angle (PA)
- Estimated Body Fat (FAT)
- Estimated Fat Free Mass (FFM)
- Estimated Total Body Water (TBW)
- Estimated Intra-Cellular Water (ICW)
- Estimated Extra-Cellular Water (ECW)
- Estimated Basal Metabolic Rate (BMR)
- Estimated Daily Energy Expenditure (DEE)
- Actual Body Mass Index (BMI)

4) Device Description

The BC application is intended to be used as a software accessory to RJL Systems' existing line of Bio-Impedance Analyzers (K830292 and K862383). The user obtains values for the Resistance and Reactance of an individual, and enters these numbers, along with the individual's name, age, height, weight, gender, activity level, frame size, and optionally, subject ID and desired target weight. These values are stored in a database to enable historical tracking, and are then used in a series of prediction equations to estimate the parameters listed above.

For estimating body composition parameters, the BC application relies on prediction equations developed as the result of clinical studies. The user is provided the opportunity to select from several different sets of equations, each assembled from one or more studies. References are provided for every set of equations, except for those contained in the original RJL BIA-103 device software.

The BC application is non-diagnostic in nature and does not express any opinions with regard to any specific disease or medical condition.

5) Substantial Equivalence Chart

		Predicate Devices		
Company	**RJL Systems**	**RJL Systems**	**Impedimed**	**BodyStat**
Device Name	**BC**	**BIA-103**	**DF-50**	**QuadScan 4000**
510(k) number		**K862383**	**K050395**	**K002835**
OTC	**YES**	**YES**	**YES**	**YES**
Indication				
Impedance	YES		YES	YES
Phase Angle	YES		YES	
Body Fat	YES	YES	YES	YES
Fat Free Mass	YES	YES	YES	YES
Total Body Water	YES	YES	YES	YES
Intra-Cellular Water	YES		YES	YES
Extra-Cellular Water	YES		YES	YES
Body Mass Index	YES		YES	YES
Basal Metabolic Rate	YES	YES	YES	YES *
Daily Energy Expenditure	YES			YES *

(*) The Indications for Use statement for the BodyStat QuadScan 4000 simply states "Metabolic Rates". However, the QuadScan 4000 reports "Basal Metabolism" and "Activity Metabolism". Activity Metabolism is an accepted synonym for "Daily Energy Expenditure".

6) Conclusion

The BC application represents an evolution of the software provided with RJL Systems' original BIA-103 device and, when used in conjunction with RJL Systems' existing line of Bio-Impedance Analyzers (K830292 and K862383) is equivalent to the Impedimed DF-50 and BodyStat QuadScan 4000.

The product comparison chart establishes that the BC software application does not raise any new questions concerning safety and effectiveness and is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 2 2007

Mr. Barry Callahan
IT Director
RJL Systems
33939 Harper Avenue
CLINTON TOWNSHIP MI 48035

Re: K070999
Trade/Device Name: BC (Body Composition Software)
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: July 17, 2007
Received: July 18, 2007

Dear Mr. Callahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070999

Device Name: __BC (Body Composition Software)_____

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- Estimated Basal Metabolic Rate (BMR)
- Estimated Daily Energy Expenditure (DEE)
- Actual Body Mass Index (BMI)

BC is intended only for use on normally healthy adults and adolescents age 9-94.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __YES_ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070999